

Appl. No. 10/755,996
Amendment Dated October 20, 2008
Reply to Office Action of August 19, 2008

Remarks:

Reconsideration of the application is requested. Claims 1, 4-10, 13, 15, 19, 30-33, 35, 37-39, 41, 43-46 remain in the application. Claims 30 and 41 have been amended.

Claim Rejections – 35 USC § 112

In paragraph 2 on page 2 of the above-identified Office action, the Examiner has rejected claims 1, 4-10, 13, 15, 19, 30-32, 35-39, and 41 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. More specifically, the Examiner has stated that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the application was filed, had possession of the claimed invention. The Examiner rejected claims 30 and 41 for reciting the phrase, “said first surface maintaining an equal distance from said second surface when moving from the wide position to the narrow position,” and stated that this features was not in the original specification.

The phrase has been amended to clarify that the device retains the same shape as the relative position of the bones is changed. The phrase in both claims 30 and 41 now reads as follows: “Said first surface maintaining an equal distance from said second surface when moving the first bone and the second bone from the wide position to the narrow position.”

Support for this feature can be seen in paragraphs [0061] through [0066] of the originally filed specification. These paragraphs describe the insertion of a wedge-shaped implant into a joint. The shape of the wedge does not change. In other words, “the first surface [of the wedge is] maintaining an equal distance from the second surface [of the wedge] [during insertion] when moving the first bone and the second bone from the wide position to the narrow position.”

Another example can be seen in Figs. 14-15. In these figures, the relative position of the bones is being changed. However, the dimensions of the implant are not changing. The orientation of the implant is being changed to change the relative position of the bones.

Appl. No. 10/755,996
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Accordingly, the claims (especially as amended) describe an invention that the inventor possessed at the time of filing the application. Accordingly, the claims meet the requirements of 35 USC 112, first paragraph.

In the last paragraph on page 2 of the Office action, the Examiner rejected claims 1, 4-10, 13, 15, 19, 30-32, 35-39, and 41 under 35 USC § 112, second paragraph. More specifically, the Examiner rejected, in claims 30 and 41, the following phrase: "Said first surface maintaining an equal distance from said second surface when moving from the wide position to the narrow position."

For the reasons discussed with regard to the 3 USC § 112, first paragraph, rejection, the phrase is believed to be clear, especially as amended. To repeat those reasons, the phrase has been amended to clarify that the device retains the same shape as the relative position of the bones is changed. The phrase in both claims 30 and 41 now reads as follows: "Said first surface maintaining an equal distance from said second surface when moving the first bone and the second bone from the wide position to the narrow position."

Accordingly, the invention described in the claims, especially claims 30 and 41, is definite and meets the requirements of 35 USC § 112, second paragraph.

Should the Examiner find any further objectionable items, counsel would appreciate a telephone call during which the matter may be resolved. The changes are neither provided for overcoming the prior art nor do they narrow the scope of the claim for any reason related to the statutory requirements for a patent.

35 USC § 103(a)

In the second full paragraph on page 3 of the Office action, the Examiner rejected claims 1, 8-9, 13, 15, 19, 30-32, 35, 37-39, 41, and 43-45 as being obvious over Stone '433 in view of Michelson '635 and Henderson et al. '175 under 35 U.S.C. § 103(a). The rejection has been noted and the claims have been amended in an effort to define more clearly the invention of the instant application. Support for the changes is found in Fig. 11 and paragraph [0088] through

Appl. No. 10/755,996
Amendment Dated October 20, 2008
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[0091] of the specification. This section and figures show a wedge member that is fixed to only one bone in a joint. The other bone merely abuts the implant and is free to rotate on the implant.

Claims 30, 41, and 43 all call for, *inter alia*, an implantable device having the following features:

a second surface configured to abut the second bone in the wide position and the narrow position, said second surface having no fastener to fix said second surface to the second bone; and

the implant being fixed to only one of the bones.

In contrast to the invention according to claims 30, 41, and 43, the prior art suggests an implant that is fixed to both bones of a joint.

The Examiner cites Stone '433 as teaching, "The implant is adapted to one connected to only one of the bones." [sic] See August 19, 2008, Office action, page 4, first full sentence.

Applicant disagrees that the art forms a *prima facie* case of obviousness as is required under 35 USC § 103(a). As discussed in MPEP § 2142, The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

Furthermore, according to MPEP § 2143.01 (III), the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007).

Appl. No. 10/755,996
Amendment Dated October 20, 2008
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Stone '433 teaches an osteotomy wedge that is inserted into an incision formed in a single bone. The osteotomy wedge must be fastened to the superior and inferior bone segments. If an osteotomy wedge were secured to only one segment, the fragile interior parts of the bone would be exposed to movement. Even if the pain were not unbearable, the bone would fracture if only secured on one side. Accordingly, there is nothing in Stone '433 to suggest changing the implant so that it only has fasteners attaching the implant to only one of the adjacent bone segments.

Michelson '635 teaches an intervertebral pillar that is used to fuse two adjacent vertebrae. The Michelson device fuses the joint. Both of the adjacent bones are fused to the implant. Nothing in Michelson '635 suggests fixing the implant to only one of the adjacent vertebrae.

Henderson '175 is another intervertebral pillar that is used to fuse two adjacent vertebrae. All of the embodiments of Henderson et al. '175 are shown fixed to both adjacent vertebrae. Nothing in Henderson et al. '175 suggests fixing the device to only one of the bones.

In addition, the Examiner should not be tempted to use the references to make a 103 rejection because one of the implants could be attached to only one of the bones in a joint, unless the Examiner can find some motivation for altering the prior art.

The other references cited by the Examiner (i.e. Jeffries '370 and Zdeblick et al. '909) do not teach or suggest an implant fixed to only one bone of a joint.

Clearly, the reference does not suggest an implant according to the claims that is connected to only one of the bones in a joint as recited in claims 30, 41, and 43 of the instant application. Accordingly, none of the references, whether taken alone or in any combination, either show or suggest the features of the independent claims. Therefore, claims 30, 41, and 43 are patentable over the art. And, because all of the dependent claims are ultimately dependent on claim 30, 41, and 43, they are believed to be patentable as well.

In view of the foregoing, reconsideration and allowance of claims 1, 4-10, 13, 15, 19, 30-33, 35, 37-39, 41, 43-46 remain in the application are solicited. In the event the Examiner should

Appl. No. 10/755,996
Amendment Dated October 20, 2008
Reply to Office Action of August 19, 2008

still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted. In the alternative, the entry of the amendment is requested as it is believed to place the application in better condition for appeal, without requiring extension of the field of search. No further search should be needed because the amendment merely clarifies features that were in the claims and were searched as part of the previous Office action.

If an extension of time for this paper is required, petition for extension is herewith made.

No fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 50-0601 (Docket No. 780-A03-021-5).

Respectfully submitted,

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